

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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ROCHE DIABETES CARE, INC., ROCHE	:
DIABETES CARE GmbH, and HOFFMANN-LA	:
ROCHE, INC.,	:
	:
Plaintiffs,	:
	:
-against-	:
	:
JMD ENTERPRISES d/b/a DKY STORE USA,	:
JMD INTERNATIONAL, DILEEP KUMAR	:
YADAV, ABHISHEK JAIN, MEDICAL	:
HUB_USA STORE, RATNAKAR SHARMA,	:
AUTHENTIC INDIAN STORE, and ATIKUR	:
RAHMAN,	:
	:
Defendants.	:
	:
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Case No. _____

COMPLAINT

JURY DEMANDED

**FILED *EX PARTE* AND UNDER SEAL
PURSUANT TO 15 U.S.C. § 1116**

Plaintiffs Roche Diabetes Care, Inc., Roche Diabetes Care GmbH, and Hoffmann-La Roche, Inc. (collectively, “Roche”), by and through their attorneys, Patterson Belknap Webb & Tyler LLP, for their Complaint against Defendants JMD Enterprises d/b/a DKY Store USA, Dileep Kumar Yadav, JMD International, Abhishek Jain, Medical Hub_USA Store, Ratnakar Sharma, Authentic Indian Store, and Atikur Rahman (collectively, “Defendants”), allege as follows:

NATURE OF THE ACTION

1. This is an anti-counterfeiting action against international manufacturers and sellers of counterfeit versions of Roche’s Accu-Chek® diabetes care medical devices. The Defendants are India-based willful counterfeiters who sell dangerous counterfeits of Roche’s Accu-Chek® medical devices to American patients through Amazon.com and other platforms. Through this action Roche seeks to put an immediate stop to the sale and distribution of these

dangerous counterfeits in U.S. commerce.

2. Patients throughout the United States and the world rely on Roche's trusted Accu-Chek® brand medical devices to monitor and treat their diabetes, including by testing their blood glucose levels daily. Patients know that Roche's Accu-Chek® medical devices are safe, sterile, and accurate.

3. The Defendant counterfeiters make their fake Accu-Chek® medical devices in back-alley Indian apartment buildings. Their counterfeits are low-quality imitations that give off a strong chemical odor and cannot be trusted to function properly. These counterfeits are then placed in counterfeit packaging meant to imitate authentic Roche U.S. packaging, including counterfeit reproductions of Roche's registered U.S. trademarks. The counterfeit packaging has salient errors, including misspelling the name of the product or referring to the manufacturer as "Roche Diabeter Care, Inc." These counterfeits are then sold to customers across the nation, including in this District.

4. The Defendants' counterfeits are likely to give false or inaccurate measurements of blood glucose levels, putting patients at risk of severe and life-threatening complications, such as hyperglycemia and over- or under-dosages of insulin. The counterfeits may also cause infection or other injury when they come into contact with patients' bloodstreams. The Defendants' counterfeits pose a serious and ongoing threat to the health and safety of American patients.

5. By utilizing Amazon's platform, the India-based Defendant counterfeiters have immediate and widespread access to the U.S. market and American consumers. The Defendants have in fact arranged for their dangerous counterfeit medical devices to be stored at Amazon warehouses across the country, including in this District. The Defendants falsely advertise their counterfeits as authentic Roche U.S. medical devices on Amazon. When U.S.

consumers unwittingly order these counterfeits on Amazon, believing them to be authentic Roche product, Amazon delivers these dangerous fake medical devices from Amazon warehouses to U.S. households and businesses, typically within 48 hours.

6. In addition to counterfeits, the Defendants also sell in U.S. commerce, through Amazon and otherwise, unlawfully diverted international versions of Accu-Chek[®] medical devices, which they falsely advertise to be authentic U.S. products. These international Accu-Chek[®] medical devices are not intended for sale in the United States and thus do not comply with U.S. Food and Drug Administration (“FDA”) regulations; they are misbranded medical devices under federal law and their sale in the United States is a strict-liability federal crime. Because they differ materially from authentic U.S. Roche products, the international products that the Defendants divert into the United States violate Roche’s U.S. trademark rights and are infringing goods under the Lanham Act.

7. To eradicate these dangerous counterfeit medical devices and unlawfully diverted medical devices from the U.S. marketplace, Roche brings this action for injunctive and monetary relief for trademark infringement in violation of Section 32 of the Lanham Act (15 U.S.C. § 1114), false descriptions and false designations of origin in commerce in violation of Section 43 of the Lanham Act (15 U.S.C. § 1125) and New York General Business Law Section 349, trademark dilution in violation of Section 43 of the Lanham Act (15 U.S.C. § 1125) and New York General Business Law Section 360-1, common law unfair competition and unjust enrichment, common law fraud and fraudulent inducement, and common law aiding and abetting fraud. Roche also seeks a Letter of Request directed to the appropriate Indian judicial authorities supporting Roche’s seeking of a seizure against the counterfeiters under Indian law.

PARTIES

Plaintiffs

8. Plaintiff Roche Diabetes Care, Inc. is a corporation organized under the laws of Delaware, with its principal place of business at 9115 Hague Road, Indianapolis, Indiana 46250.

9. Plaintiff Roche Diabetes Care GmbH is a corporation organized under the laws of Germany, with its principal place of business at Sandhofer Str. 116 68305, Mannheim, Baden-Württemberg, Germany.

10. Plaintiff Hoffmann-La Roche, Inc. is a corporation organized under the laws of New Jersey with a principal place of business at 150 Clove Road, Great Notch, 8th Floor, Little Falls, NJ.

Defendants

11. Defendant JMD Enterprises d/b/a DKY Store USA (“JMD Enterprises”) is a corporation that is registered in India under Indian Goods and Services Tax Identification Number (“GSTIN”) 07ALOPY9462D1ZE, with its principal place of business in New Delhi, India. JMD Enterprises owns and/or controls the DKY Store USA storefront (“DKY”) on Amazon.com. Both through DKY and under its own name, JMD Enterprises uses its Amazon storefronts to sell counterfeit, misbranded, and unlawfully diverted medical devices in U.S. commerce.

12. Defendant JMD International is company registered in India under GSTIN 07BAGPA4853C1Z5, with its principal place of business in New Delhi, India. Among other things, JMD International owns and/or operates a storefront under its name on Amazon.com and uses its Amazon storefront to sell counterfeit, misbranded, and unlawfully diverted Accu-Chek[®] medical devices in U.S. commerce.

13. Defendant Dileep Kumar Yadav is a citizen of India and is the founder, principal, owner, and/or operator of JMD Enterprises and its DKY storefront, and is a moving and active force behind JMD Enterprises's sale of counterfeit, misbranded, and unlawfully diverted Accu-Chek[®] medical devices in U.S. commerce. Yadav founded JMD Enterprises and is the individual associated with JMD Enterprises's GSTIN. Yadav is the owner of various real properties at which JMD and DKY operate their counterfeiting business. Yadav was until recently listed as the point of contact for DKY on its Amazon storefront.

14. Yadav is also a principal and/or agent of JMD International and is a moving and active force behind JMD International's sale of counterfeit, misbranded, and unlawfully diverted Accu-Chek[®] medical devices in U.S. commerce.

15. Defendant Abhishek Jain is a citizen of India and the founder, principal, owner, and/or operator of JMD International, and is a moving and active force behind JMD International's sale of counterfeit, misbranded, and unlawfully diverted Accu-Chek[®] medical devices in U.S. commerce. Jain founded JMD International and is the individual associated with JMD International's GSTIN.

16. Jain is also a principal and/or agent of JMD Enterprises and is a moving and active force behind JMD Enterprise's sale of counterfeit, misbranded, and unlawfully diverted Accu-Chek[®] medical devices in U.S. commerce. Jain financed the purchase of one or more properties owned by Yadav at which JMD Enterprises operate their counterfeiting business.

17. Defendant Medical Hub_USA Store ("Medical Hub") is a company with its principal place of business in Rishikesh, Uttarakhand, India. Among other things, Medical Hub owns and operates an Amazon.com storefront under its name and uses that storefront to sell counterfeit, misbranded, and unlawfully diverted Accu-Chek[®] medical devices in U.S.

commerce.

18. Defendant Ratnakar Sharma is a citizen of India and a principal, owner, and/or operator of Medical Hub, and is a moving and active force behind Medical Hub's sale of counterfeit, misbranded, and unlawfully diverted Accu-Chek® medical devices in U.S. commerce.

19. Defendant Authentic Indian Store is a company with a principal place of business in India. Authentic Indian Store has on occasion conducted business as Indian Authentic Store. Among other things, Authentic Indian Store owns and/or operates a storefront under its name on Amazon.com and uses that storefront to sell misbranded and unlawfully diverted Accu-Chek® medical devices in U.S. commerce.

20. Defendant Atikur Rahman is a citizen of India and a principal, owner, and/or operator of Authentic Indian Store, and is a moving and active force behind Authentic Indian Store's sale of misbranded and unlawfully diverted medical devices in U.S. commerce.

JURISDICTION AND VENUE

21. The Court has subject matter jurisdiction over this action under the Lanham Act, 15 U.S.C. §§ 1114, 1125; under 28 U.S.C. §§ 1331, 1332, 1338(a), 1338(b), and 1367; and under general principles of ancillary and pendent jurisdiction.

22. The amount of damages at issue exceeds \$75,000, exclusive of interest and costs.

23. This Court has personal jurisdiction over the Defendants because they regularly transact or have transacted business in New York, including in the Eastern District of New York, by selling, offering for sale, and marketing what they falsely claim to be authentic U.S. Roche Accu-Chek® medical devices, but which are instead counterfeit, misbranded, and/or unlawfully diverted Accu-Chek® medical devices. Each of the Defendants delivered counterfeit

and/or unlawfully diverted Accu-Chek® products into this District both directly and through Amazon. As alleged in further detail below, each of the corporate Defendants has sold counterfeit Accu-Chek® medical devices and/or unlawfully diverted and misbranded Accu-Chek® medical devices to investigators in the Eastern District of New York. Each of the individual defendants was a moving and active force behind their respective corporations' sale of such counterfeit and infringing Accu-Chek® medical devices in the Eastern District of New York.

24. The Court also has personal jurisdiction over each of the Defendants pursuant to Fed. R. Civ. P. 4(k) and N.Y. C.P.L.R. 301 and 302. The Court also has personal jurisdiction over each of the Defendants because the tortious acts described herein (which occurred in New York, among other places), were conducted and/or directed by each of the Defendants.

25. The Defendants regularly do or solicit business, engage in a persistent course of conduct, and derive substantial revenue from goods used or consumed in New York State.

26. The Defendants intended, knew, expected, or should reasonably have expected that the tortious acts described herein would have consequences in New York State.

27. The Defendants derive substantial revenue from interstate and international commerce.

28. Venue is proper in the Eastern District of New York pursuant to 28 U.S.C. § 1391(b) and (c) in that a substantial part of the events or omissions giving rise to the claim occurred in this district, including through Defendants' delivery of counterfeit and infringing products delivered into this District, as well as through counterfeit and infringing products that were sold by Defendants through Amazon storefronts that are stored in, and shipped by, Amazon

from one or more Amazon warehouses located in this District. As set forth above, each Defendant is subject to personal jurisdiction in this District.

FACTS

29. Roche is the manufacturer of Accu-Chek[®] brand diabetes care medical devices, including Accu-Chek[®] glucometers, blood glucose test strips, and lancets. Diabetes is a life-long and potentially deadly disease, and millions of Americans rely on Accu-Chek[®] products every day to monitor, control, and treat their diabetes.

30. Roche is one of the leading manufacturers of diabetes care medical devices in the United States and the world. Roche's Accu-Chek[®] brand diabetes care products are well-recognized for their high quality, safety, and efficacy.

31. In the United States, Roche's Accu-Chek[®] blood glucose test strips and lancets can be purchased directly by consumers with or without a prescription. In addition to being sold at pharmacies throughout the nation, these Accu-Chek[®] products are also available through online stores and marketplaces, including Amazon.com.

32. The Defendants, third-party counterfeiters with no connection to Roche, use their Amazon storefronts to sell counterfeit, misbranded, and/or unlawfully diverted Accu-Chek[®] test strips and lancets into the United States. The Defendants are willful counterfeiters who operate out of back-alley apartments in India, and they would remain purely local criminals if they did not take advantage of Amazon's platform to falsely advertise, sell, store, and ship their counterfeits throughout the United States. Instead of being sold in shady local bazaars, the Defendants' counterfeits are now being offered to untold numbers of American consumers when they open Amazon and search for "Accu-Chek."

33. The Defendants' counterfeit and misbranded medical devices pose an

immediate danger to the health and safety of American patients.

34. Roche's authentic Accu-Chek Softclix[®] lancets are high-quality sterile medical devices designed to pierce the skin, penetrate the blood-skin barrier, and draw blood for testing. The Defendants' fake Accu-Chek Softclix[®] lancets are of obviously inferior quality and are made and stored in unknown conditions, putting American patients at risk of injury and infection.

35. The Defendants' counterfeit Accu-Chek[®] test strips are expired or nearly expired products that are removed from their original authentic packaging under unknown conditions, have their original labelling stripped by a process that leaves behind a strong chemical odor, and are re-packaged into counterfeit U.S. packaging with fake expiration dates that falsely makes the counterfeits appear to be factory-new U.S. product with a long remaining shelf life. Using Defendants' counterfeit test strips could provide inaccurate blood glucose readings to American patients who rely on Accu-Chek[®] strips to give them information they use to monitor and treat a potentially deadly disease.

36. In addition to selling counterfeit Accu-Chek[®] products, the Defendants also use their Amazon storefronts to sell unlawfully diverted Accu-Chek[®] test strips that were manufactured and packaged for international markets, and that the Defendants import back into the United States. There are several important and material differences between these international test strips and U.S. test strips – *i.e.*, test strips that Roche manufactures for sale in the United States and distributes into the United States. Among other things, the international Accu-Chek[®] test strips do not comply with FDA regulations and requirements and are unlawful to sell in the United States. Indeed, international Accu-Chek[®] test strips sold in the United States are misbranded medical devices under the Food & Drug Administration Act, and their sale or


distribution in the United States is a strict-liability federal crime under 21 U.S.C § 333(a).

I. Roche's Trademarks and Trade Dress

37. Roche is the owner of a family of registered U.S. trademarks including, among others, the following trademarks that appear on packaging for Accu-Chek SmartView[®], Accu-Chek Guide[®], Accu-Chek Aviva[®], Accu-Chek Active[®], and Accu-Chek Instant[®] blood glucose test strips and Accu-Chek Softclix[®] lancets (collectively referred to herein as the “Accu-Chek Marks”):

- Roche Diabetes Care GmbH's “ACCU-CHEK[®]” trademark was registered on the Principal Register of the United States Patent and Trademark Office on November 14, 2000, as U.S. Registration No. 2,403,536.
- Roche Diabetes Care GmbH's “ACCU-CHEK SMARTVIEW[®]” trademark was registered on the Principal Register of the United States Patent Office on October 23, 2012, as U.S. Registration No. 4,230,563.
- Roche Diabetes Care GmbH's “ACCU-CHEK NANO SMARTVIEW[®]” trademark was registered on the Principal Register of the United States Patent Office on October 16, 2012, as U.S. Registration No. 4,226,844.
- Roche Diabetes Care GmbH's “SOFTCLIX[®]” trademark was registered on the Principal Register of the United States Patent Office on July 6, 1993, as U.S. Registration No. 1,780,139.
- Roche Diabetes Care GmbH's “ACCU-CHEK GUIDE[®]” trademark was registered on the Principal Register of the United States Patent Office on August 1, 2017, as U.S. Registration No. 5,256,607.
- Roche Diabetes Care GmbH's “ACCU-CHEK GUIDE ME[®]” trademark was registered on the Principal Register of the United States Patent Office on April 28, 2020, as U.S. Registration No. 6,042,931.
- Roche Diabetes Care GmbH's “ACCU-CHEK NANO[®]” trademark was registered on the Principal Register of the United States Patent Office on September 25, 2012, as U.S. Registration No. 4,214,217.
- Roche Diabetes Care GmbH's “ACCU-CHEK AVIVA[®]” trademark was registered on the Principal Register of the United States Patent Office on March 21, 2006, as U.S. Registration No. 3,071,846.
- Roche Diabetes Care GmbH's “ACCU-CHEK AVIVA COMBO[®]” trademark was registered on the Principal Register of the United States Patent Office on April 7,

2009, as U.S. Registration No. 3,602,826.

- Roche Diabetes Care GmbH's "ACCU-CHEK AVIVA CONNECT[®]" trademark was registered on the Principal Register of the United States Patent Office on July 8, 2014, as U.S. Registration No. 4,561,864.
- Roche Diabetes Care GmbH's "ACCU-CHEK AVIVA EXPERT[®]" trademark was registered on the Principal Register of the United States Patent Office on April 7, 2009, as U.S. Registration No. 3,602,825.
- Hoffmann-La Roche, Inc.'s  trademark was registered on the Principal Register of the United States Patent Office on December 26, 2017, as U.S. Registration Nos. 5,363,165, 5,363,167, and 5,363,168;

38. Roche uses distinctive packaging (the "Accu-Chek Trade Dress") to distinguish its Accu-Chek[®] products in the marketplace. Roche has used this distinctive packaging for over forty years. The Accu-Chek Trade Dress is arbitrary, non-functional, and distinctive.

39. The Accu-Chek Marks and Accu-Chek Trade Dress have been extensively and continuously used by Roche, and are inherently distinctive and/or have become distinctive through the acquisition of secondary meaning.

40. Roche sells over 700 million test strips every year in the United States alone. The sale of Accu-Chek[®] test strips, lancets, and other Accu-Chek[®] brand products has been tremendously successful in part due to Roche's marketing and promotion of the Accu-Chek[®] brand throughout the country and the world.

41. The Accu-Chek[®] brand is recognized in the United States and throughout the world as representing high-quality, reliable medical devices manufactured and distributed by Roche. Accu-Chek[®] test strips and lancets are sold in pharmacies throughout the United States and world.

42. As a result of Roche's extensive advertising and promotion of Accu-Chek[®] test strips and lancets in connection with the Accu-Chek Marks and Accu-Chek Trade

Dress, Roche's widespread and long-running sale of Accu-Chek[®] test strips and lancets, and the celebrity that the Accu-Chek Marks and Accu-Chek Trade Dress have achieved, blood glucose test strips and lancets bearing Accu-Chek Marks and Accu-Chek Trade Dress have been and are now recognized by the consuming public in the United States and in the trade as originating from a single source: Roche.

43. Test strips and lancets bearing the Accu-Chek Marks and Accu-Chek Trade Dress have come to be known by the purchasing public throughout the United States and abroad as medical devices and blood glucose test strips of the highest quality. As a result, the Accu-Chek Marks and Accu-Chek Trade Dress and the goodwill associated with them are of inestimable value to Roche.

44. Roche has used and is currently using the Accu-Chek Marks and Accu-Chek Trade Dress in commerce and in connection with its sale of Accu-Chek[®] test strips, lancets, and other products, and plans to continue such use in the future.

II. Roche's Authentic Accu-Chek[®] Test Strips and Lancets

45. Roche's Accu-Chek[®] test strips and lancets are industry-leading diabetes care medical devices relied upon by millions of patients in the United States and worldwide.

46. Roche has manufactured a number of lines of blood glucose test strips under the Accu-Chek[®] brand, including Accu-Chek SmartView[®]. Accu-Chek SmartView[®] test strips are high-quality medical devices that give accurate readings with a sample size of just 0.6 microliters of blood.

47. Accu-Chek SmartView[®] test strips are stored in specially designed vials that bear a label that lists the test strips' lot number, catalogue number, and expiration date. Roche warns patients that Accu-Chek[®] test strips should be stored within the vial with the lid tightly closed, and within certain parameters for air temperature and humidity. Roche also warns

patients never to use expired test strips or test strips where the expiration date is illegible or unknown.

48. Accu-Chek Softclix[®] lancets are premium, thin-gauge, bevel-cut lancets specially designed to ensure smooth entry into the skin and precision of insertion to minimize pain to the patient.

49. Accu-Chek Softclix[®] lancets are also specifically designed to work with Roche's Accu-Chek Softclix[®] lancing device, which contains precision guided technology also designed to reduce pain. Roche warns patients to only use authentic Accu-Chek Softclix[®] lancets with its Accu-Chek Softclix[®] lancing devices, as non-authentic lancets may damage the lancing device and/or cause it to malfunction.

50. All Roche Accu-Chek[®] medical devices are manufactured in state-of-the-art facilities using specialized equipment, strict specifications, and extensive quality assurance measures.

III. Roche's Investigation and Testing of the Defendants' Counterfeits

51. In late March 2024, a whistleblower reached out to Roche's online marketplace monitoring vendor, stating that certain India-based companies were selling counterfeit Roche test strips in the United States on Amazon.com.

52. Under the direction and supervision of counsel, Roche launched an investigation, including by making test buys of Accu-Chek[®] products from the identified sellers. Upon receiving the test purchases, Roche was able to quickly verify the products were not authentic.

53. Recognizing the counterfeits being sold through Amazon.com as a threat to American patients, Roche moved quickly to expand its investigation and identify the counterfeiters. Under the direction and supervision of counsel, Roche arranged for private

investigators to make numerous purchases of Accu-Chek® products from Indian sellers on online marketplaces, including Amazon.com. All of the products that were the subject of these test buys were advertised and marketed as authentic U.S. Roche Accu-Chek® products. The test purchases were delivered to addresses within this District.

54. Defendants JMD Enterprises, JMD International, and Medical Hub_USA Store, by and through the actions of their respective individual Defendants, sold multiple counterfeit Accu-Chek® products to Roche's investigators in this District.

55. Of the test purchases made from Defendants on Amazon.com, most of the counterfeits were stored in Amazon warehouses and delivered directly by Amazon. In fact, a number of the counterfeits were delivered by Amazon from Amazon warehouses within this District, including Queens and Long Island. Amazon currently has untold numbers of these dangerous counterfeit medical devices in its warehouses across the country, ready to deliver to unsuspecting American consumers at the click of a button. The Defendants themselves also directly shipped, from India, a smaller number of counterfeit or unlawfully diverted Accu-Chek® products to Roche's investigators in this District.

56. Roche never gave permission to any of the Defendants to utilize Roche's registered trademarks, or to manufacture, market, sell, or distribute these counterfeit and unlawfully diverted Accu-Chek® products in the United States.

A. The Counterfeit Accu-Chek Softclix® Lancets

57. Through its examination and testing, Roche has confirmed that all of the purported Accu-Chek Softclix® lancets sold by the Defendants are counterfeit. The lancets themselves are counterfeit: no aspect of that product was manufactured or licensed by Roche, and the counterfeit lancets are of obvious lesser quality than authentic Accu-Chek Softclix® lancets. Furthermore, the packaging containing the lancets is a counterfeit imitation of Roche's

authentic packaging, including unauthorized copies of Roche's registered U.S. trademarks.

58. Although clearly designed to resemble authentic Accu-Chek Softclix[®] lancets, the counterfeit lancets sold by Defendants have numerous differences from authentic Roche Accu-Chek Softclix[®] lancets.

1. The Counterfeit Lancet Needles

59. Authentic Accu-Chek Softclix[®] lancets are thin, sharp, bevel-cut needles used to puncture the skin and draw a small amount of blood for testing. These needles come in a plastic encasement with a removable cap that protects the needle itself. Authentic Accu-Chek Softclix[®] lancets are specifically designed to be inserted into Accu-Chek Softclix[®] lancing devices, which among other things allow patients to adjust the length of the needle that punctures the testing site. The thinness, length, and sharpness of authentic Accu-Chek Softclix[®] lancets are essential to providing the precision, pain-minimizing blood draw for which the Accu-Chek Softclix[®] brand has become known.

60. The counterfeit lancets sold by Defendants feature lower-quality needles that are significantly shorter and less sharp than authentic Accu-Chek Softclix[®] lancets, and thus will not and cannot provide the precision, pain-minimizing blood draw that authentic Accu-Chek Softclix[®] lancets provide. The counterfeits will also not function optimally, or function at all, in Accu-Chek Softclix[®] lancing devices, and may malfunction or damage the lancing device.

61. Authentic Accu-Chek Softclix[®] lancets are manufactured to the highest standards that, among other things, ensure the lancets are sterile and safe to use to puncture patients' skin. The Defendants' counterfeits are not manufactured by Roche, and are created, packaged, and stored in unknown conditions. Roche cannot vouch for the sterility, safety, or efficacy of the counterfeit lancets.

2. The Counterfeits' Plastic Encasements

62. Authentic Accu-Chek Softclix[®] lancets come in a plastic encasement with a removable circular cap that protects the metal needle itself. In the authentic product, the body of the plastic encasement has two small circular holes through which the needle itself is visible; in the Defendants' counterfeits, there are three such holes in the plastic encasement.

63. In authentic Accu-Chek Softclix[®] lancets, the removable plastic cap sits atop a small horizontal plastic ridge that aids in the removal of the cap. The Defendants' counterfeit lancets are missing that horizontal ridge. The encasement of authentic Accu-Chek Softclix[®] lancets is made of high-quality plastic with smooth edges. The plastic encasement of Defendants' counterfeit lancets has sharp out-jutting shards of plastic on the cap and on the base of the encasement, indicating that the counterfeits were removed or "punched out" of cheap plastic molding.

64. More generally, the plastic used in the encasement of the counterfeits is of a noticeably thinner and lower quality as compared to Roche's high-quality, authentic product. For example, the plastic cap on the counterfeits is difficult to remove and can leave plastic residue on the needle itself. This does not occur with authentic Accu-Chek Softclix[®] lancets.

65. The Defendants' counterfeit lancets also show signs of inconsistent manufacturing processes. For example, even within the same box of counterfeit lancets, there is significant variation in the coloring of the plastic encasements: some are different shades of white, and others have a noticeable blue tint.

3. The Counterfeit Accu-Chek Softclix[®] Packaging

66. The packaging for Defendants' counterfeit lancets is also intended to mimic authentic Roche packaging, including the use of unauthorized copies of the Roche registered trademarks that appear on authentic Roche packaging. However, there are differences

between the Defendants' counterfeit packaging and authentic Roche packaging that prove the Defendants' packaging is fake.

67. Perhaps most obviously, the Defendants' counterfeit packaging misspells the name of the product: the counterfeits use the name "Accu-Chek Softclick," whereas the real product name is spelled "Accu-Chek Softclix." The counterfeits also use the ™ symbol after these brand names, whereas authentic Roche packaging uses the ® symbol, because its trademarks are registered.



68. The counterfeit lancets also arrive inside the counterfeit box sealed inside a cloudy plastic bag. There is no such plastic bag used in the packaging of authentic Accu-Chek Softclix® lancets. The plastic bag that holds the counterfeits is often filled with small pieces of plastic detritus – i.e., additional plastic shards that had broken off the plastic encasement of the counterfeits.

69. In addition to these differences, there are also differences in font, layout, and construction of the Defendants' counterfeit packaging and authentic Roche Accu-Chek Softclix® packaging that confirm the Defendants' packaging is counterfeit.

4. Roche's Initial Testing of the Counterfeit Lancets Confirms They Are Defective Fakes

70. Initial testing of the Defendants' counterfeit lancets confirmed that they are low-quality, defective fakes.

71. Authentic Accu-Chek Softclix[®] lancets fit snugly into the Accu-Chek Softclix[®] lancing device, with an audible “click.” The counterfeits do not fit snugly into an Accu-Chek Softclix[®] lancing device and do not consistently produce the “click.”

72. Authentic Accu-Chek Softclix[®] lancets can be ejected from the lancing device by pushing a plunger on the device. The counterfeits do not consistently eject from the lancing device as intended, but instead needed to be pried out of the lancing device by hand, creating a risk of injury to the patient.

73. Accu-Chek Softclix[®] lancing devices allow the consumer to adjust the depth of the needle puncture by adjusting a dial on the side of the device. Using one of the same testing methods that Roche uses to quality-test authentic lancets, Roche tested the counterfeit lancets by firing them into a silicone block covered with a thin layer of aluminum. Authentic Accu-Chek Softclix[®] lancets will puncture the aluminum layer and the silicon block at any depth setting. The counterfeits failed to even leave a visible mark on the aluminum layer, let alone puncture the silicone, on several different settings – meaning the counterfeits completely failed to function.

B. The Counterfeit Accu-Chek SmartView[®] Test Strips

74. Roche’s examination of the Defendants’ purported Accu-Chek SmartView[®] test strips confirms that they are counterfeits.

75. The Defendants’ counterfeits consist of expired or near-expired test strips removed from their original packaging under unknown conditions and their vial labels removed, which are then repackaged into a counterfeit reproduction of Roche’s U.S. packaging, but bearing fake lot numbers, fake serial numbers, and fake expiration dates that falsely give the appearance of the test strips being factory-new, unexpired U.S. product with a long shelf life.

1. The Fake Vial Labels, Expiration Dates, and Serial and Lot Numbers

76. Both the boxes and the vial labels for Defendants' counterfeit Accu-Chek SmartView[®] test strips bear fake serial numbers, fake lot numbers, and fake expiration dates. Using internal records and marks appearing on the bottom of the vials, Roche was able to determine the actual expiration dates of the test strips originally packed in those vials. The fake expiration dates on the counterfeit boxes and vial labels make it appear as though the product has a long remaining shelf life, when in fact the strips are expired or near-expired. All of the counterfeit Accu-Chek SmartView[®] strips that each of the Defendants sold to Roche's investigators bore the exact same serial numbers, lot numbers, and expiration dates. It is clear the counterfeiters made a single set of counterfeit packaging and reused it for all of their counterfeits, at least for a significant period of time.



Counterfeit Accu-Chek SmartView[®] packaging with identical serial numbers

77. The serial numbers on the authentic packaging of Accu-Chek SmartView[®] test strips are unique, per-box identifiers: the serial numbers never repeat from box to box. The

fact that the Defendants' counterfeit Accu-Chek SmartView[®] boxes all bore the same serial number is proof they are counterfeit. Any distributor of Accu-Chek[®] test strips who received boxes with identical serial numbers would know they are fakes.

78. The authentic labels originally on the vials containing the test strips were removed by the counterfeiters. Several of the Defendants' counterfeits had vials that gave off a strong, chemical-like odor upon opening the carton. No such odor exists in authentic Accu-Chek SmartView[®] packaging. The odor from the counterfeits suggests that harsh, currently unknown chemicals were used to remove the original labelling on the vials. The use of chemicals to remove the original vial labels could damage the test strips inside, including by causing the active ingredients of the strips to prematurely degrade.

79. In addition, the counterfeiters may have used heat guns to remove the original authentic labels from the vials. Use of a heat gun or other heat source can damage the test strips inside and cause the active ingredients of the strips to prematurely degrade.

80. After the original vial labels were removed, the fake labels applied by the counterfeiters onto the vials are typically misaligned and show signs of peeling and bubbling.

81. In authentic Accu-Chek SmartView[®] packaging – on both the box and the vial label – the serial and lot numbers, expiration dates, and other information on the variable-print area is laser ablated, a high-speed process that leaves a slight but noticeable texture on the surface. The Defendants' counterfeits used regular ink printing on the counterfeit boxes and counterfeit vial labels.

2. The Counterfeit Boxes

82. The counterfeit Accu-Chek SmartView[®] test strips sold by Defendants are packaged in counterfeit boxes that are intended to duplicate Roche's authentic U.S. Accu-Chek SmartView[®] packaging, and include unauthorized copies of Roche's registered U.S. trademarks.

83. There are errors on the Defendants’ counterfeit packaging, some more obvious than others. For example, the counterfeit packaging bears an obvious typographical error: on a side panel, it claims the product was manufactured by “Roche **Diabeter** Care, Inc.” (emphasis added). The correctly spelled name is, of course, Roche Diabetes Care, Inc.

Roche Diabetes Care, Inc.
9115 Hague Road
Indianapolis, IN 46256

Authentic Packaging

Roche Diabeter Care, Inc.
9115 Hague Road
Indianapolis, IN 46256

Counterfeit Packaging

84. The construction of the counterfeit Accu-Chek SmartView® boxes is also different and of a lower quality than authentic Accu-Chek SmartView® packaging. For example, the top flap of authentic Accu-Chek SmartView® boxes is sealed by a machine that puts precise dots of adhesive on specified areas of the flap. The counterfeit boxes, in contrast, appear to be glued together by hand, with globs of adhesive that sometimes extend beyond the top flap and that cause the box to tear upon opening.



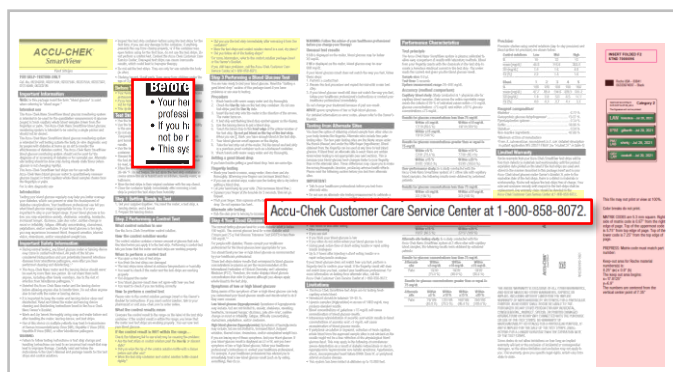
Counterfeit packaging

3. The Counterfeit Patient Instructional Inserts

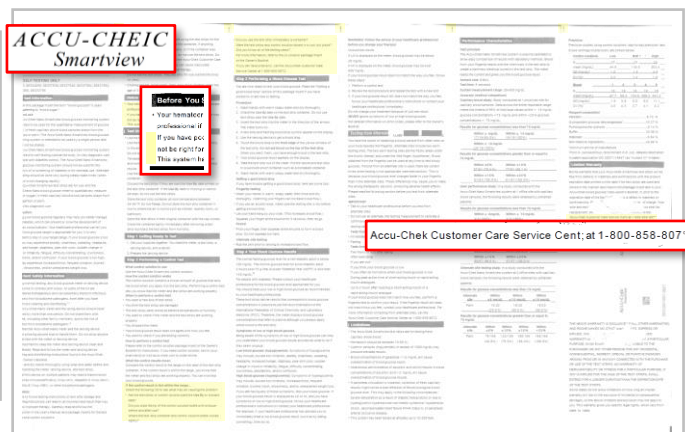
85. Finally, the patient instructional inserts included inside Defendants' counterfeit Accu-Chek SmartView® products are also counterfeit, and also make unauthorized copies of Roche's registered U.S. trademarks.

86. The Defendants' counterfeit Accu-Chek SmartView® instructional inserts contain numerous errors that do not and would not occur on Roche's authentic instructional inserts. For example, they contain obvious errors demonstrating that these inserts are counterfeit copies, including: misspellings throughout the insert; missing bullet points omitting instructional information; incorrect service center telephone numbers; and incorrect markings and symbols.

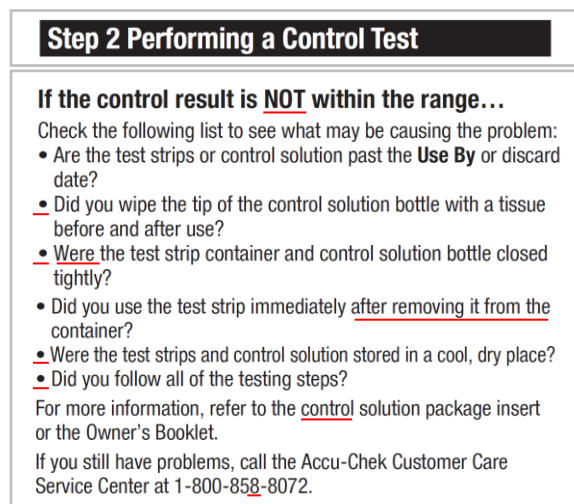
Authentic Patient Insert



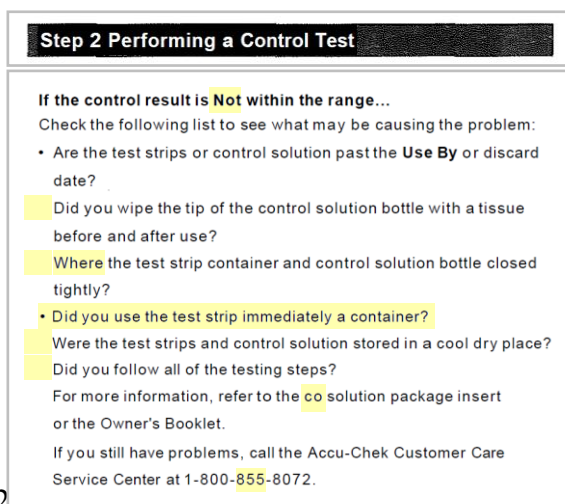
Counterfeit Patient Insert



Authentic Patient Insert



Counterfeit Patient Insert



87. Moreover, the counterfeit instructional inserts are folded incorrectly as compared to authentic inserts. Roche's authentic instructional inserts are machine-folded using specialized machinery, which the counterfeiters were unable to replicate.

IV. The Defendants' Counterfeit Medical Devices Pose a Serious and Immediate Threat to Patient Health and Safety

88. The Defendants' counterfeit Accu-Chek® lancets and test strips are being sold in large quantities to U.S. consumers who are purchasing the products on an extremely well-known online marketplace, Amazon.com. Consumers have no idea the products are counterfeit when they order them. The Defendants' counterfeits put those patients' health and safety at risk.

89. Roche cannot vouch for the sterility or safety of the Defendants' counterfeit lancets, which are low-quality fakes meant to imitate Roche's authentic, high-quality Accu-Chek Softclix® lancets. Lancets are designed to penetrate patients' skin, break the blood-skin barrier, and produce a sufficient amount of blood for diabetics to test their blood sugar. The Defendants' low-quality counterfeits may injure patients who use them, and more concerning, may not be sterile or otherwise safe to penetrate patients' skin.

90. Roche also cannot vouch for the safety or efficacy of the Defendants' counterfeit SmartView test strips. The Defendants' counterfeits were created using expired or near-expired test strips that will expire well before the fake expiration date on the box; use of expired strips can lead to inaccurate test results.

91. Moreover, the Defendants' counterfeits are created from test strips that were removed from their original packaging under unknown conditions, with the vials containing the strips appearing to have been subjected to a harsh chemical process and/or concentrated blasts of high heat to remove the original labelling. There is therefore good cause to be concerned that Defendants' counterfeit test strips are damaged or contaminated, which again can

lead to inaccurate test results, as well as posing a contamination risk to patients who put these counterfeits in contact with blood extracted from a testing site on their body.

92. In addition, authentic Accu-Chek SmartView[®] test strips must be stored at or below 30 degrees Celsius, or 86 degrees Fahrenheit, as noted on the packaging of the authentic test strips. When stored above that temperature, the test strips can become damaged, including by prematurely degrading the active ingredients of the test strips. The counterfeiters store the counterfeit boxes of Accu-Chek SmartView[®] test strips in back-alley residential apartments in rooms without air conditioning in New Delhi and elsewhere in India, where temperatures can routinely exceed 110 degrees Fahrenheit in the summer.

93. Moreover, international shipping regularly exposes goods to high temperatures for prolonged periods of time. Roche arranges for its authentic Accu-Chek[®] test strips to be shipped internationally subject to specific requirements for temperature. The counterfeiters do not follow such rigorous requirements when they import the counterfeits in the United States, thus potentially exposing the test strips to conditions that could prematurely degrade the active ingredients.

94. Accu-Chek[®] test strips that are expired, exposed to excessive heat, or otherwise damaged may contain active ingredients that have degraded to the extent that they will not give an accurate reading of a patients' blood glucose levels. When such test strips with degraded active ingredients do give a reading, they can give a reading that overstates the amount of glucose in the patients' blood.

95. Diabetics use Accu-Chek[®] medical devices to monitor their blood sugar and manage and treat diabetes, a life-long and potentially deadly disease. Patients with diabetes rely on blood glucose test results to, among other things, determine the levels of insulin they should self-inject. Inaccurately high test results from the Defendants' counterfeits could cause

patients to unknowingly inject themselves with an overdose of insulin. Insulin overdoses can have severe negative consequences for patients, up to and including coma and death. Indeed, the FDA has publicly warned that using blood glucose test strips that have been previously opened by someone other than the consumer “may potentially cause infection or lead to inaccurate test results, which can cause serious harm, including death.”¹

V. The Defendants Also Sell Unlawfully Diverted, Misbranded Accu-Chek® Medical Devices in the United States, in Violation of Roche’s Trademark Rights

96. In its investigation and test buys from Defendants, including test buys made on Amazon.com, Roche learned that in addition to selling counterfeit Accu-Chek Softclix® lancets and Accu-Chek SmartView® test strips, the Defendants are selling several other once-authentic but unlawfully diverted international Accu-Chek® medical devices. These unlawfully diverted international Accu-Chek® products are manufactured and packaged by Roche for markets outside the United States, and the Defendants are illegally importing these international Accu-Chek® medical devices into the United States. These unlawfully diverted international Accu-Chek® products are materially different in numerous ways from authentic U.S. Accu-Chek® products – i.e., from the Accu-Chek® products that Roche manufactures and packages for sale into the United States.

97. The only Accu-Chek® products that Roche sells and distributes in the United States are U.S. Accu-Chek® products. Roche does not sell or distribute in the United States any of the international Accu-Chek® products – i.e., Accu-Chek® products that Roche manufactures and packages for markets outside the United States.

¹ *FDA warns about risks of using home use test strips that are pre-owned or not authorized for sale in U.S., including those for glucose, warfarin*, U.S. FOOD & DRUG ADMIN. (April 8, 2019), available at <https://www.fda.gov/news-events/press-announcements/fda-warns-about-risks-using-home-use-test-strips-are-pre-owned-or-not-authorized-sale-us-including>.

98. In the United States, Accu-Chek® medical devices are heavily regulated by the FDA. All U.S. Accu-Chek® products are compliant with FDA regulations, including with regard to the manufacture and packaging of the products, and their patient instructional inserts. International Accu-Chek® test strips, on the other hand, are manufactured and packaged for sale in countries outside the United States with their own regulatory authorities and requirements, and so do not comply with all FDA regulations.

99. Indeed, when sold inside the United States, international Accu-Chek® test strips constitute misbranded medical devices under the Food & Drug Administration Act, and their sale or distribution in the United States is a strict-liability federal crime under 21 U.S.C § 333(a).

100. The international Accu-Chek® products that Defendants are unlawfully selling in the United States include Accu-Chek Guide®, Accu-Chek Aviva®, Accu-Chek Active®, and Accu-Chek Instant® blood glucose test strips.

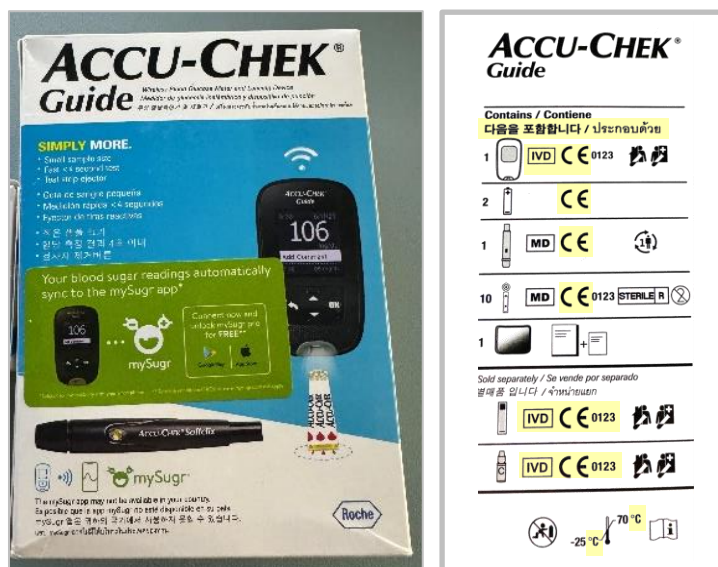
101. As noted above, Accu-Chek® test strips must be stored within specified temperature ranges, and the Defendants' storage practices routinely expose the international Accu-Chek® test strips in their inventory to temperatures well beyond the allowable maximum, potentially damaging the test strips and rendering them unusable or inaccurate. The same is likely true with regard to the Defendants' shipment of the international test strips from India to the United States, as these shipments are not subject to Roche's shipping specifications and requirements.

102. Beyond the damage that the Defendants' storage and shipping practices can cause to the products, the international Accu-Chek® test-strip products differ in numerous material ways from the U.S. Accu-Chek® test strips that Roche sells domestically.

103. For example, international Accu-Chek® test strips have foreign languages

on the box and instructional inserts, whereas U.S. Accu-Chek® test strips come in English-language packaging. Many international Accu-Chek® products being sold in the United States by Defendants do not contain English at all.

104. Moreover, the packaging for international Accu-Chek® test strips lacks numerous aspects present on U.S. Accu-Chek® test strip packaging that are material to American consumers.



105. The packaging for every box of U.S. Accu-Chek® test strips also provides FDA-required written warnings and instructions, including “Do not reuse” and “For *in vitro* diagnostic use.” The outer package label of international Accu-Chek® test strips does not provide these warnings.

106. Roche also uses significantly different trade dress for domestic Accu-Chek® products and international Accu-Chek® products, including different box colors and designs. Diabetes is a life-long disease, and American patients who use Accu-Chek® test strips are very familiar with the U.S. Accu-Chek Trade Dress. Those consumers are likely to be confused upon buying on Amazon.com what is advertised as U.S. Accu-Chek® test strips, but is

in reality an unlawfully diverted box of international Accu-Chek® test strips.

107. International Accu-Chek® test strips also come with instructional inserts that are materially different from the instructional inserts that are included with U.S. Accu-Chek® test strips. For example, both instructional inserts tell patients where on their body they may draw a blood sample. However, the international inserts instruct the patients that they may draw blood from sites on the body that do not appear in the FDA-approved U.S. instructional inserts.

108. There are myriad other differences between the U.S. and international patient inserts, including: different units of measurement; an explanation of symbols on the U.S. insert that does not exist on international inserts; differences in the charts describing the blood glucose systems' product characteristics; study references in the U.S. insert that do not exist in the international inserts; and differences in the safety reporting instructions between U.S. and international inserts.

109. Individually and as a whole, these differences between U.S. and international Accu-Chek® test strips are material to U.S. consumers and would be confusing to U.S. consumers who are expecting the languages, regulatory markings, trade dress measurements, instructional inserts, and other aspects of an authentic U.S. product intended for sale in the United States. This is particularly so for users of this product who are managing a lifelong disease and make daily use of Roche's diabetes care medical devices, and thus look to Roche for consistency and reliability.

VI. Defendants' Infringing Sales Interfere with Roche's Quality-Control Measures

110. Moreover, authentic Accu-Chek® test strips and lancets are manufactured with a catalogue number and lot number. Roche uses catalogue and lot numbers to track where the test strips are shipped and then to monitor them if any safety or quality issues arise. When a

recall is warranted, for example, Roche notifies the regulatory agencies in the countries that were authorized to receive the impacted catalogue and lot number, informing them of the particular issue and seeking their guidance. Roche then issues recall notices, which are only sent to regions and/or consumers that are authorized to have received the particular subset of product that is the subject of the recall. By using targeted recalls, Roche spares consumers from seeing inapplicable recall notices, which can lead to consumer confusion, disposal of non-recalled devices, and desensitization to recall notices that can result in future recalls being ignored.

111. When Accu-Chek[®] blood glucose testing medical devices are repackaged into counterfeit packaging and, as such, separated from manufacturing information including catalogue and lot numbers, it eliminates Roche's ability to perform a targeted product recall.

112. Furthermore, when international Accu-Chek[®] medical devices are unlawfully diverted into the United States from the region for which they were manufactured, Roche's ability to perform a targeted recall is undermined, because the impacted products are no longer in the authorized region into which they were distributed.

113. Moreover, U.S. boxes of Accu-Chek[®] test strips prominently display Roche's U.S. toll-free consumer hotline, where consumers can call with questions or to report any quality issues or adverse events. The lack of a U.S. toll-free number on the unlawfully diverted international test strips further undermines that important quality-assurance function.

114. Finally, as described above, the counterfeit repackaging process also destroys the integrity of the product, rendering it impossible for Roche to vouch for the quality, safety, or efficacy of the medical device. And the unlawfully diverted international test strips are subjected to the same storage and shipping conditions that expose the product to unknown temperatures and storage conditions, potentially damaging the product and rendering it inaccurate or unusable.

VII. The Counterfeiters Use Amazon to Take Advantage of American Patients

115. The Defendants are knowing, criminal counterfeiters living and operating in impoverished areas of New Delhi and elsewhere in India. They operate their counterfeiting operations out of back-alley apartments and cramped storefronts. Without access to American consumers through an American sales platform, the Defendants' counterfeiting would not be economically viable or would be a purely local problem and could be dealt with locally. But by opening storefronts on Amazon.com, Defendants are willfully marketing these dangerous counterfeits directly to American consumers, and benefit by being associated with one of the most famous American companies in existence. These dangerous counterfeit medical devices are now stored in Amazon warehouses throughout the United States and delivered by Amazon delivery vehicles to U.S. customers.

116. The Defendants do directly ship their counterfeit and infringing products to the United States, but they also participate in Amazon's Fulfillment by Amazon ("FBA") program. Through FBA, Amazon agrees to receive, store, and accept orders on behalf of the counterfeiters; to pick, pack, and ship the counterfeit goods; and to provide customer service for the counterfeiters. Through FBA, the counterfeiters ship products directly to Amazon fulfillment centers, and Amazon stores and ships the products directly to U.S. customers. Amazon, in return, receives a sizable percentage of the revenue from the counterfeit sales.

117. Indeed, as recently as May 2, 2024, a customer left a negative review on Amazon's platform, complaining that he had ordered test strips from DKY, and had received a different product. Amazon crossed out the language of the negative review—the language appears on Amazon's website with a line through it—and replied on behalf of the counterfeiter, writing: "This item was fulfilled by Amazon, and we [Amazon] take responsibility for this fulfillment experience."

118. As another example, a different customer wrote the following review on Amazon in March 2024 concerning the supposed Accu-Chek Softclix[®] lancets she purchased from DKY: “These lancets are fake. They will not fit in your device properly and won’t work. Do not buy!”

119. The Defendants’ purported business model on Amazon makes no sense. The Defendants claim to purchase U.S. medical devices, import those products to India, and then turn around and sell those U.S. medical devices back to U.S. customers, re-exporting them back from India into the United States. And the Defendants claim to do all that at discount pricing, while also paying sizable fees to Amazon, and still turn a profit. That is an economic impossibility, and an obvious falsehood.

120. Concerningly, many American consumers who purchased the Defendants’ counterfeits on Amazon did not even realize they are purchasing from a third-party seller, let alone a seller purporting to import and re-export U.S. medical devices into and out of India.

121. When a U.S. consumer searches Amazon.com for a particular product and clicks on the corresponding link, the Amazon webpage will feature on the right side of the screen a large window known as the Amazon “buy box,” which displays the price and shipping information for that product, along with large “Add to Cart” and “Buy Now” buttons. Those “Add to Cart” and “Buy Now” buttons are linked to a particular seller on the Amazon marketplace; Amazon automatically determines which seller will be associated with the “buy box” based on a proprietary algorithm. The vast majority of Amazon shoppers purchase goods from whatever seller is associated with the “buy box” when they look up a product on Amazon. Many of those consumers incorrectly believe that by clicking on those buttons they are buying from a trusted source, such as the manufacturer or an authorized distributor.

122. In some cases, the seller associated with the Amazon “buy box” for Accu-

Chek[®] products was a Defendant, and the product the U.S. consumer received after clicking on “Add to Cart” or “Buy Now” was in fact a counterfeit or unlawfully diverted, non-FDA-approved medical device. Those consumers had no idea that they were being directed to purchase fake or unlawfully diverted Accu-Chek[®] products from a criminal in India.

FIRST CLAIM FOR RELIEF

Federal Trademark Infringement 15 U.S.C. §1114(1)(a) (Lanham Act Section 32)

123. Roche incorporates each paragraph of this Complaint as if fully set forth herein.

124. Roche is the owner of all right, title and, interest in and to the Accu-Chek Marks and Accu-Chek Trade Dress.

125. Defendants, without authorization, have imported into the United States, and/or distributed and/or sold in the United States, and/or received in interstate commerce, either a reproduction, counterfeit, copy or colorable imitation of the Accu-Chek Marks and the Accu-Chek Trade Dress in connection with the sale, offering for sale, distribution, or advertising of counterfeit Roche products.

126. Defendants, without authorization, have also imported into the United States, and/or distributed and/or sold in the United States, and/or received in interstate commerce, either a reproduction, counterfeit, copy or colorable imitation of the Accu-Chek Marks and/or the Accu-Chek Trade Dress in connection with the sale, offering for sale, distribution, of diverted international Accu-Chek[®] products featuring the Accu-Chek Marks and/or Accu-Chek Trade Dress, which products are materially different from the U.S. Accu-Chek[®] products authorized by Roche for sale in the United States and which are not subject to and undermine Roche’s quality-control measures.

127. The Defendants’ actions are likely to cause confusion, mistake, or

deception as to the source of origin, sponsorship, or approval of the counterfeit and the diverted international Accu-Chek® products, including in that purchasers and others in this judicial district and elsewhere in the United States are likely to believe Roche authorizes and controls the sale of Defendants' counterfeit and diverted international Accu-Chek® products, or that Defendants are associated with or related to Roche or are authorized by Roche to sell Accu-Chek® products in the United States.

128. Defendants' actions constitute willful infringement of Roche's exclusive rights in the Accu-Chek Marks and Accu-Chek Trade Dress. Defendants are directly, contributorily, and vicariously liable for their infringement.

129. Defendants' acts have been committed deliberately and willfully, with knowledge of Roche's exclusive rights and goodwill in the Accu-Chek Marks and Accu-Chek Trade Dress, and with knowledge of the infringing nature of the marks when used in connection with both the counterfeit and diverted international Accu-Chek® products. Defendants' acts have been committed with bad faith and the intent to cause confusion, to cause mistake, and/or to deceive.

130. As a result of Defendants' trademark infringement, Roche has suffered and will continue to suffer substantial and irreparable injury, loss and damage to its rights in and to the Accu-Chek Marks and Accu-Chek Trade Dress, and damage to the goodwill associated therewith, for which it has no adequate remedy at law. If not restrained, Defendant will have unfairly derived and will continue to derive illicit income, profits, and business opportunities as a result of their acts of infringement.

131. As the acts alleged herein constitute infringement of the Accu-Chek Marks and Accu-Chek Trade Dress under 15 U.S.C. § 1114(1)(a), and as Roche has no adequate remedy at law, Roche is entitled to injunctive relief as well as to Defendants' profits, Roche's

damages, and other remedies provided by 15 U.S.C. §§ 1116, 1117 and 1118, and to reasonable attorneys' fees and prejudgment interest pursuant to 15 U.S.C. § 1117.

SECOND CLAIM FOR RELIEF

Federal Trademark Infringement 15 U.S.C. §1114(1)(b) (Lanham Act Section 32)

132. Roche incorporates each paragraph of this Complaint as if fully set forth herein.

133. Roche is the owner of all right, title and, interest in and to the Accu-Chek Marks and Accu-Chek Trade Dress.

134. Defendants, without authorization, have imported into the United States, and/or distributed and/or sold in the United States, and/or received in interstate commerce, either a reproduction, counterfeit, copy or colorable imitation of the Accu-Chek Marks and the Accu-Chek Trade Dress in connection with the sale, offering for sale, distribution, or advertising of counterfeit Roche products.

135. Defendants, without authorization, have also imported into the United States, and/or distributed and/or sold in the United States, and/or received in interstate commerce, either a reproduction, counterfeit, copy or colorable imitation of the Accu-Chek Marks and/or the Accu-Chek Trade Dress in connection with the sale, offering for sale, distribution, of diverted international Accu-Chek® products featuring the Accu-Chek Marks and/or Accu-Chek Trade Dress, which products are materially different from the U.S. Accu-Chek® products authorized by Roche for sale in the United States and which are not subject to and undermine Roche's quality-control measures.

136. The Defendants' actions are likely to cause confusion, mistake, or deception as to the source of origin, sponsorship, or approval of the counterfeit and the diverted international Accu-Chek® products, including in that purchasers and others in this judicial

district and elsewhere in the United States are likely to believe Roche authorizes and controls the sale of Defendants' counterfeit and diverted international Accu-Chek[®] products, or that Defendants are associated with or related to Roche or are authorized by Roche to sell Accu-Chek[®] products in the United States.

137. Defendants' actions constitute willful infringement of Roche's exclusive rights in the Accu-Chek Marks and Accu-Chek Trade Dress. Defendants are directly, contributorily, and vicariously liable for their infringement.

138. Defendants' acts have been committed deliberately and willfully, with knowledge of Roche's exclusive rights and goodwill in the Accu-Chek Marks and Accu-Chek Trade Dress, and with knowledge of the infringing nature of the marks when used in connection with both the counterfeit and diverted international Accu-Chek[®] products. Defendants' acts have been committed with bad faith and the intent to cause confusion, or to cause mistake and/or to deceive.

139. As a result of Defendants' trademark infringement, Roche has suffered and will continue to suffer substantial and irreparable injury, loss, and damage to its rights in and to the Accu-Chek Marks and Accu-Chek Trade Dress, and damage to the goodwill associated therewith, for which it has no adequate remedy at law. If not restrained, Defendant will have unfairly derived and will continue to derive illicit income, profits, and business opportunities as a result of their acts of infringement.

140. As the acts alleged herein constitute infringement of the Accu-Chek Marks and Accu-Chek Trade Dress under 15 U.S.C. § 1114(1)(b), and as Roche has no adequate remedy at law, Roche is entitled to injunctive relief as well as to Defendants' profits, Roche's damages, and other remedies provided by 15 U.S.C. §§ 1116, 1117 and 1118, and to reasonable attorneys' fees and prejudgment interest pursuant to 15 U.S.C. § 1117.

THIRD CLAIM FOR RELIEF

Federal Unfair Competition 15 U.S.C. § 1125(a)(i)(A) (Lanham Act Section 43(a))

141. Roche incorporates each paragraph of this Complaint as if fully set forth herein.

142. Defendants have, without authorization, imported into the United States and/or distributed and/or sold in the United States and/or received in interstate commerce, both counterfeit Accu-Chek® products and diverted international Accu-Chek® products featuring the Accu-Chek Marks and/or Accu-Chek Trade Dress, which products are materially different from the U.S. Accu-Chek® test strips authorized by Roche for sale in the United States and which are not subject to and undermine Roche's quality-control measures. Such use is likely to cause confusion, or to cause mistake and/or to deceive as to the affiliation, connection or association of Defendants with Roche, and as to the origin, sponsorship or approval by Roche of Defendants' counterfeit and diverted international Accu-Chek® test strips and the commercial activities related to Defendants' counterfeit and diverted international U.S. Accu-Chek® test strips.

143. Defendants' acts constitute a false representation and a false designation of origin in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

144. Defendants' acts have been committed willfully, with knowledge of Roche's exclusive common-law rights and goodwill in the Accu-Chek Marks and Accu-Chek Trade Dress, as well as with bad faith and the intent to cause confusion or mistake, and/or to deceive.

145. Roche has suffered and, if Defendants are not enjoined, will continue to suffer great and irreparable injury, loss, and damage to its rights in and to the Accu-Chek Marks and Accu-Chek Trade Dress and to the goodwill associated therewith for which Roche has no adequate remedy at law.

146. If not restrained, Defendants will have unfairly derived and will continue to derive illicit income, profits, and business opportunities as a result of their acts of infringement.

147. As the acts alleged herein violate Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and as Roche has no adequate remedy at law, Roche is entitled to injunctive relief and to Defendants' profits, Roche's damages, and other remedies provided by 15 U.S.C. §§ 1116, 1117 and 1118, and to reasonable attorneys' fees and prejudgment interest pursuant to 15 U.S.C. § 1117.

FOURTH CLAIM FOR RELIEF

Common-Law Unfair Competition

148. Roche incorporates each paragraph of this Complaint as if fully set forth herein.

149. Defendants' acts constitute an infringement of Roche's trademark rights in violation of common law, including the common law of the State of New York and elsewhere.

150. As a result of Defendants' acts Roche has suffered and, if Defendants are not enjoined, will continue to suffer great and irreparable injury, loss, and damage to its rights in and to the Accu-Chek Marks and Accu-Chek Trade Dress, and to the goodwill associated therewith for which Roche has no adequate remedy at law.

FIFTH CLAIM FOR RELIEF

State Law Trademark Dilution

151. Roche incorporates each paragraph of this Complaint as if fully set forth herein.

152. Roche's Accu-Chek Marks and Accu-Chek Trade Dress are distinctive under state law, including New York General Business Law § 360-1.

153. Defendants' acts are likely to cause dilution by blurring and/or tarnishment, and damage the business reputation of Roche in violation of state law, including New York General Business Law § 360-1.

154. Through their acts, Defendants have injured and are continuing to injure Roche's business reputation and/or have diluted and are continuing to dilute the distinctive quality of the Accu-Chek Marks and Accu-Chek Trade Dress, in violation of state law, including New York General Business Law § 360-1.

155. Defendants' acts greatly and irreparably damage Roche and will continue to do so unless restrained by this Court. Therefore, Roche is without an adequate remedy at law and is entitled to, among other things, an order enjoining and restraining Defendants from selling counterfeit Accu-Chek® test strips, and diverted international Accu-Chek® test strips.

SIXTH CLAIM FOR RELIEF

State Law Deceptive Business Practices

156. Roche incorporates each paragraph of this Complaint as if fully set forth herein.

157. Defendants' acts were consumer-oriented.

158. Defendants' acts were materially misleading.

159. Defendants' acts have caused and are continuing to cause injury to Roche in violation of state law, including New York General Business Law § 349.

160. Defendants' acts greatly and irreparably damage Roche and will continue to do so unless restrained by this Court. Therefore, Roche is without an adequate remedy at law and is entitled to, among other things, an order enjoining and restraining Defendants from selling Roche products.

SEVENTH CLAIM FOR RELIEF

Unjust Enrichment

161. Roche incorporates each paragraph of this Complaint as if fully set forth herein.

162. The Defendants made false representations and material omissions in fraudulently selling counterfeit and diverted international boxes of Accu-Chek® products, including by representing the products to be authentic U.S. Accu-Chek® products, on consumer-facing online marketplaces at a lower cost than was legally available in the United States.

163. As a result of these false representations and material omissions, Defendants wrongfully obtained a monetary benefit to which they were not legally entitled.

164. Defendants have no right to retain these unjust gains.

165. If Defendants are permitted to keep this monetary benefit, it would be manifestly unjust.

166. By selling both counterfeit and diverted international Accu-Chek® products in the United States, Defendants have been unjustly enriched at Roche's expense in violation of the common law of New York and elsewhere.

EIGHTH CLAIM FOR RELIEF

Importation of Goods Bearing Infringing Marks 15 U.S.C. § 1124

167. Roche incorporates each paragraph of this Complaint as if fully set forth herein.

168. By illegally importing both counterfeit Accu-Chek® products and diverted international Accu-Chek® products from foreign countries with the intent of inducing consumers into believing that the products are authentic and authorized for resale in the United States, Defendants have violated 15 U.S.C. § 1124.

169. Roche has been, and continues to be, damaged by Defendants' activities and conduct. Defendants have profited thereby and, unless their conduct is enjoined, Roche's reputation and goodwill will continue to suffer irreparable injury that cannot adequately be calculated or compensated by money damages. Accordingly, Roche is entitled to injunctive relief under 15 U.S.C. § 1116.

NINTH CLAIM FOR RELIEF

False Description and Designation of Origin in Commerce

170. Plaintiffs incorporate each paragraph of this Complaint as if fully set forth herein.

171. In violation of 15 U.S.C. § 1125(a)(1)(A), Defendants, independently and in conspiracy with one another, in connection with the counterfeit and the unlawfully diverted Roche products, used in commerce a slogan, trade dress, word, term, name, symbol or device, or any combination thereof, or a false designation of origin, false or misleading description of fact or false or misleading representation of fact, which was or is likely to cause confusion or to cause mistake, or to deceive as to an affiliation, connection, or association with Roche.

172. Defendants' actions constitute willful infringement of Plaintiffs' exclusive rights in the Accu-Chek Marks and the Accu-Chek Trade Dress.

173. As a direct and proximate result of Defendants' conduct, Plaintiffs have suffered irreparable harm to the valuable Accu-Chek Marks and the Accu-Chek Trade Dress, and to their reputation in the industry. Unless Defendants' conduct is restrained, Plaintiffs will continue to be irreparably harmed.

174. Plaintiffs have no adequate remedy at law that will compensate for the continued and irreparable harm they will suffer if Defendants' acts are allowed to continue.

175. As a direct and proximate result of Defendants' conduct, Plaintiffs have

suffered damages to the valuable Accu-Chek Marks and the Accu-Chek Trade Dress, and other damages in an amount to be proved at trial.

TENTH CLAIM FOR RELIEF

Federal False Advertising

176. Plaintiffs incorporate each paragraph of this Complaint as if fully set forth herein.

177. In violation of 15 U.S.C. § 1125(a)(1)(B), Defendants, independently and in conspiracy with one another, in connection with the sale of the counterfeit Roche products and diverted international Roche products, used a slogan, trade dress, word, term, name, symbol, or device or any combination thereof, or a false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which in commercial advertising or promotion, misrepresents the nature, characteristics, and qualities of the counterfeit Roche products.

178. Defendants advertised, marketed and promoted the counterfeit Roche products to the public, and/or to specific segments of the public, using Plaintiffs' Accu-Chek Marks and Accu-Chek Trade Dress, as well as other intellectual property belonging to Plaintiffs.

179. Defendants' actions constitute willful infringement of Plaintiffs' exclusive rights in the Accu-Chek Marks and the Accu-Chek Trade Dress.

180. As a direct and proximate result of Defendants' conduct, Plaintiffs have suffered irreparable harm to the valuable Accu-Chek Marks and Accu-Chek Trade Dress, and to their reputation in the industry. Unless Defendants' conduct is restrained, Plaintiffs will continue to be irreparably harmed.

181. Plaintiffs have no adequate remedy at law that will compensate for the continued and irreparable harm they will suffer if Defendants' acts are allowed to continue.

182. As a direct and proximate result of Defendants' conduct, Plaintiffs have suffered damages to the valuable Accu-Chek Marks and Accu-Chek Trade Dress, and other damages in an amount to be proved at trial.

PRAYER FOR RELIEF

WHEREFORE, Roche demands judgment against all Defendants as follows:

- (a) an order entering judgment in favor of Roche against Defendants, jointly and severally;
- (b) an order temporarily restraining, and preliminarily and permanently enjoining Defendants from engaging in the unlawful behavior described above, and from selling, or distributing, any Accu-Chek® or other Roche products;
- (c) an order awarding Roche damages in an amount to be determined, including without limitation actual damages, punitive damages, statutory damages, and an accounting of and/or disgorgement of Defendants' profits;
- (d) an order awarding Roche a trebling of damages;
- (e) an order awarding Roche pre-judgment and post-judgment interest;
- (f) an order awarding Roche reasonable attorneys' fees and other costs; and
- (g) for such additional relief as the Court finds just, equitable, and appropriate.

JURY DEMAND

Roche hereby requests a jury trial on all claims and issues asserted in this
Complaint.

DATED: May 20, 2024
New York, New York

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